



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington, DC 20204

OCT 23 1997

0799 '97 DEC 16 P1:41

Ms. Karen A. Weaver
Dilling and Dilling
150 North Wacker Drive
Chicago, Illinois 60606

Dear Ms. Weaver:

This is in response to your letter of October 20, 1997 to the Food and Drug Administration (FDA) pursuant to section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the act), on behalf of Interplexus, Inc., Kent, Washington. Your submission states that Interplexus, Inc. is making, among other claims, the following claims for the product "AP Mag:"

"...For upset stomach conditions"

"...is also helpful with parasitic conditions"

Section 403(r)(6) of the act makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggests that it is intended to treat, prevent, cure, or mitigate diseases, namely gastric distress conditions and parasite infections. These claims do not meet the requirements of section 403(r)(6) of the act. These claims suggest that this product is intended for use as a drug within the meaning of section 201(g)(1)(B) of the act, and that it is subject to regulation under the drug provisions of the act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,

James T. Tanner, Ph.D.
Acting Director
Division of Programs and Enforcement Policy
Office of Special Nutritionals
Center for Food Safety
and Applied Nutrition

975-0163

LET84

DILLING AND DILLING
ATTORNEYS AT LAW
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ESTABLISHED 1917

ALBERT W. DILLING
1892 - 1969

JOHN M. MANN
PATENT AND TRADEMARK
COUNSEL

0800 '97 OCT 21 1997
October 20, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

Via Overnight Delivery

Re: Notification of Statements of Nutritional Support

Dear Sir:

Enclosed is the original and two copies of an executed notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

If necessary, please address future correspondence to our firm.

Sincerely yours,

DILLING AND DILLING



Karen A. Weaver

Enclosure

75560 CALLE DEL SUR
INDIAN WELLS, CALIFORNIA 92210
(619) 568-1924
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CALIFORNIA LEGAL ASSOCIATE
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55313

October 20, 1997

Office of Special Nutritionals (HFS-450)
Center for Food Safety and
Applied Nutrition
Food and Drug Administration
200 C Street, SW
Washington, DC 20204

0801 '97 DEC 16 P1:42

Re: Statements of Nutritional Support

Dear Sir:

Consider the following as notification of Statements of Nutritional Support as required under Section 101.93 of 21 Code of Federal Regulations.

Distributor Name & Address:

InterPlexus, Inc.
6620 South 192nd Place, J-105
Kent, Washington 98032

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
1) "Digestive system tonic and rejuvenative"; and "Promotes regularity".	Beleric Myrobalan, Chebulic Myrobalan and Indian Gooseberry	Trifal
2) "A support to the pancreas".	Biotin, Chromium Nicotinate, Gymnema Sylvestre, Pterocarpus Marsupium, Basil, Momardica Charantic, Neem and Betaine	Bio Gymnema
3) "Helps with gastrointestinal conditions"; "For upset stomach conditions, to enhance appetite, and to increase digestive activity"; "Blood purifiers"; and "Offers nutritional support for the gastrointestinal system and is also helpful with parasitic conditions".	Bael, Chinaberry, Bitter Melon, Basil Leaves, Long Pepper and Berberis Aristata	AP Mag
4) "To prevent sluggish metabolism"; and "To tone and stimulate the digestive system".	Commiphora Mukal (Guggal)	Guggal-Lip
5) "To support the liver, skin and G.I. conditions"; and "Liver-supportive herb".	Phyllanthus Amarus	Livit 1

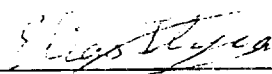
see
docket

97S-0163

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
6) "To support and facilitate deep internal detoxification, while nurturing and strengthening the liver"; and "Supports and balances liver functions".	Tinospora Cardifolia, Boerhaavia Diffusa, Tephrosia Purpura, Picrorhiza Kurroa, Phyllanthus Amarus, Swertia Chirata, Calotropis Gigantea, Raphanus Sativa, Berberis Aristata, Terminalia Chebula, Embelica Officinalis, Solanum Nigrum and Andrographis Paniculata	Livit 2
7) "Can help optimize the stress response".	Calcium, Magnesium and Phosphorus	Seriphos
8) "Enhances the pro-anabolic state"; "Provides important cofactors in the utilization of DHEA for protein synthesis"; "Promotes glycemic control for a more steady energy delivery"; "Helps in pregnenolone synthesis and utilization"; "Promotes the adaptation of individuals to chronic stress"; and "Use in chronic fatigue, lack of vitality, a tendency toward fat accumulation, emotional exhaustion and chronic stress states".	Pantothenic Acid, Zinc, Pyridoxine, Biotin and Copper	Adapt
9) "Helps protect the cardiovascular system".	Grape Skin Extract	Flavoplex/C
10) "Plays an important symbiotic role in optimizing the intestinal flora"; "Lactobacilli attach to the intestinal wall and form a layer which can competitively block the attachment of other undesirable organisms"; and "Binds effectively to human intestinal epithelium".	L. Acidophilus and Bifidobacterium	MicroCell H M F
11) "Provides a broad spectrum of protective antioxidants"; "It is used as an antiscorbutic, i.e., to prevent scurvy or bleeding gums caused by Vitamin C deficiency"; and "Nutritional properties are due to the abundance of naturally occurring antioxidant and other accessory nutrients".	Indian Gooseberry	AmlaPlex

<u>Statement Text</u>	<u>Name of Subject Dietary Ingredient(s)</u>	<u>Brand Name</u>
12) "Active in the breakdown of fats, carbohydrates and proteins"; "Breaks down food proteins"; and "Breaks down fats and oils".	Protease, Bromelain, Papain, Amylase and Lipase	Polyzyme
14) "Optimizes your health"; "Biotin helps maintain blood sugar control"; "Biotin helps regulate protein synthesis"; and "Biotin is important in the metabolism of essential fatty acids".	Biotin, Folic Acid, Thiamin, Riboflavin, B12 Coenzyme, Pyridoxine, Niacinamide, Pantothenic Acid, d-alpha Tocopheryl Succinate, Vitamin A, Vitamin D3, Vitamin K, Zinc (Citrate), Chromium (Nicotinate), Selenium (Sodium), Iodine (Potassium Iodide), Molybdenum (Sodium), Manganese (Citrate) and Magnesium (Malate, Ethanolamine)	Vyta.Myns

The information contained in this notice is complete and accurate. The above distributor has substantiation that the statements are truthful and not misleading.



Dr. Elias Ilyia
President
InterPlexus, Inc.